

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 1, 2023

LIANBIO
(Exact name of registrant as specified in its charter)

Cayman Islands
(State or other jurisdiction
of incorporation)

001-40947
(Commission
File Number)

98-1594670
(IRS Employer
Identification No.)

103 Carnegie Center Drive, Suite 309
Princeton, NJ
(Address of principal executive offices)

08540
(Zip Code)

(Registrant's telephone number, including area code): (609) 486-2308

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American depositary shares, each representing 1 ordinary share, \$0.000017100448 par value per share	LIAN	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01. Regulation FD Disclosure.

As previously disclosed, LianBio (the “Company”) is hosting a virtual event for analysts and investors to discuss the topline data from EXPLORER-CN and an overview of the China market opportunity for mavacamten, pending regulatory approval, at 8:00 a.m. EDT / 8:00 p.m. CST on May 1, 2023. A copy of the slide presentation that will be used during the Company’s virtual event is attached hereto as Exhibit 99.1.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Slide Presentation by LianBio, dated May 1, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

LIANBIO

By: /s/ Yizhe Wang
Yizhe Wang
Chief Executive Officer

Date: May 1, 2023



EXPLORER-CN Topline Data Results and Mavacamten China Commercial Opportunity Call

May 1, 2023



The information herein contains statements about future expectations, plans and prospects for LianBio. The words “expect,” “believe,” “continue,” “estimate,” “potential,” “will,” “plan,” “anticipate” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements are not statements of historical fact nor are they guarantees or assurances of future performance. Forward-looking statements in this presentation include, but are not limited to, statements regarding LianBio’s ability to accelerate patient access to innovative medicines and its clinical development capabilities in China; LianBio’s plans to use the data from EXPLORER-CN and its pharmacokinetics study to support registration of mavacamten in China; mavacamten’s potential as a therapeutic agent in indications outside of obstructive hypertrophic cardiomyopathy; LianBio’s expectations regarding its ability to and the timeframe within which it expects to bring mavacamten to market in China and its expectations with respect to the market opportunity for mavacamten, if approved, in China; and LianBio’s expectations and initiatives with respect to its commercial readiness strategy. Forward-looking statements are based on LianBio’s expectations and assumptions and are subject to inherent uncertainties, risks and changes in circumstances that may cause actual results to materially and adversely differ from those set forth in or implied by such forward-looking statements, including those risks and uncertainties that are described under the heading “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2022, as well as discussions of potential risks, uncertainties and other important factors in our subsequent filings with the Securities and Exchange Commission. LianBio undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. These forward-looking statements should not be relied upon as representing LianBio’s views as of any date subsequent to the date hereof.

In addition, topline and interim data from clinical trials may not be indicative of final results, and the results of early clinical trials may not be indicative of the results of later clinical trials. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical and clinical trials have nonetheless failed to obtain marketing approval of their products. There is a risk that additional nonclinical and/or clinical safety studies will be required by the China National Medical Products Administration or similar regulatory authorities in other jurisdictions, or that subsequent studies will not match results seen in prior studies. As a result, topline data should be viewed with caution until the final data are available.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third party sources and LianBio’s own internal estimates and research. While LianBio believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of any information obtained from third party sources. In addition, the third party information included in this presentation may involve a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while LianBio believes its own internal research is reliable, such research has not been verified by any independent source.



Yizhe Wang, Ph.D.

Chief Executive Officer, LianBio



Obstructive Hypertrophic Cardiomyopathy (oHCM)

Treatment and diagnosis in China today

Zhuang Tian, M.D., Professor of Cardiology, Peking Union Medical College Hospital; EXPLORER-CN Investigator



Phase 3 EXPLORER-CN Topline Data Review

Clinical and regulatory update

Michael Humphries, FRCP, Chief Scientific Advisor, LianBio



Mavacamten Potential

Clinical development strategy in other diseases of diastolic dysfunction

Brianna Sun, Head of CV Medical, LianBio



Commercial Readiness Strategy

Mavacamten in oHCM

Pascal Qian, Chief Commercial Officer and General Manager of China, LianBio



Q&A

Yizhe Wang, Ph.D., Yi Larson, Pascal Qian, Michael Humphries



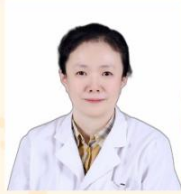
Mission: To catalyze the development and accelerate availability of paradigm-shifting medicines for patients in China and major Asian markets

Where We Started

- Vision to **accelerate patient access** to innovative medicines
- **Decrease the time** it has historically taken to bring new medicines into China
- Leverage newly available regulatory paths that **shorten timeline to approval**
- **Design and execute bespoke development strategies**, taking into account local clinical practice and local regulator considerations

Where We Are

- First program in-licensed has met primary endpoint in **first pivotal trial**
- NDA accepted with **priority review** by China's National Medical Products Administration
- Designed clinical programs based on key endpoints to **support commercialization**
- Potential for mavacamten approval in China roughly **2 years after approval in the U.S.**



HCM Diagnosis and Treatment in China Today

Zhuang Tian, M.D.

- Professor of Cardiology, and Deputy Director of the Internal Medical Department, Peking Union Medical College Hospital
- Member of Chinese Society of Rare Diseases
- Member and Secretary of the Heart Failure Group of Chinese Society of Cardiology
- Member of the Standing Committee of the Clinical Pharmacy Branch of the Beijing Medical Association
- Deputy Director of the Cardiovascular Precision Medicine and Rare Diseases Group of the Fifth Committee of the Cardiovascular Physician Branch of the Chinese Medical Doctor Association
- China Executive Director of the Rare Disease Branch of the Research Hospital Association
- Expertise in the diagnosis and treatment of heart failure, cardiomyopathy, pulmonary hypertension and imaging studies such as echocardiography.
- Author of more than 60 papers and editor of 2 books
- Investigator, EXPLORER-CN

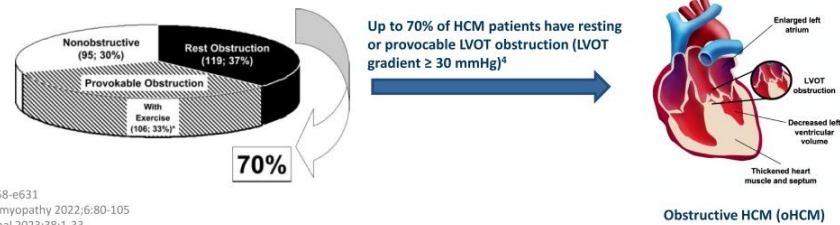


HCM Clinical Definition¹⁻³

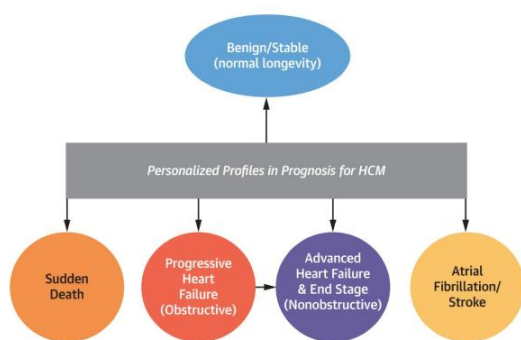
- HCM is a disease state in which morphologic expression is confined solely to the heart. It is characterized predominantly by **left ventricular hypertrophy (LVH)** in the absence of another cardiac, systemic, or metabolic disease capable of producing the magnitude of hypertrophy evident in a given patient and for which a **disease-causing sarcomere (or sarcomere-related) variant** is identified, or genetic etiology remains unresolved.

HCM Clinical Diagnosis in Adults¹⁻³

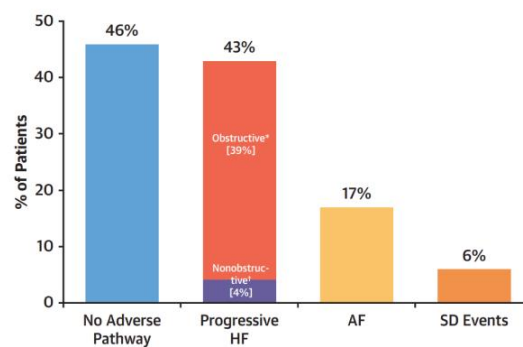
- A diagnosis of HCM can be established by imaging, with **echocardiography** or **cardiac magnetic resonance (CMR)** showing a maximal end-diastolic wall thickness **≥15 mm** anywhere in the left ventricle, in the absence of another cause of hypertrophy in adults. More limited hypertrophy (**13-14 mm**) can be diagnostic when present in family members of a patient with HCM or in conjunction with a positive genetic test.



1. Circulation 2020;142:e558-e631
 2. Clin J Heart Fail & Cardiomyopathy 2022;6:80-105
 3. Chinese Circulation Journal 2023;38:1-33
 4. Circulation 2006;114:2232-9



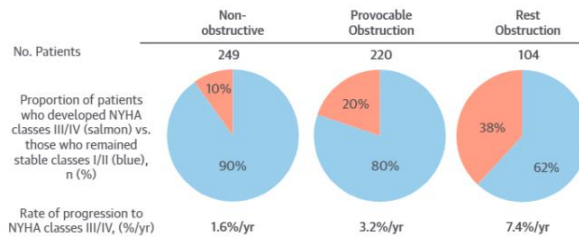
Clinical profiles and prognostic pathways



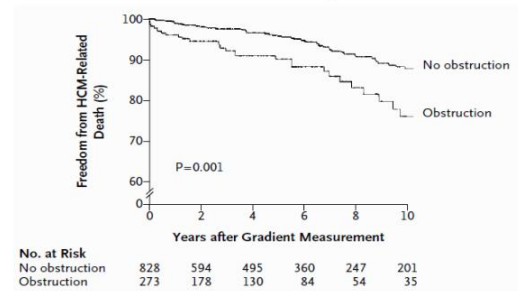
Percentage of HCM patients experiencing adverse clinical pathways



Annual rate of progression to severe heart failure in oHCM is **3.2-7.4%**¹



The risk of HCM-related death is **twice** that in non-obstructive HCM patients²

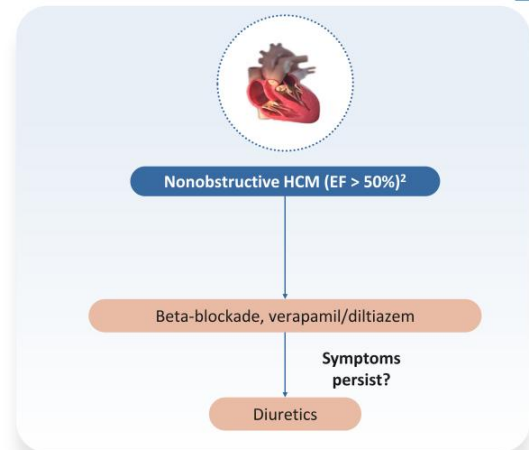
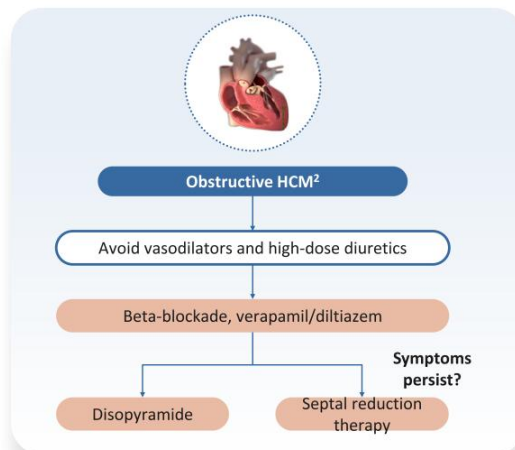


LVOT obstruction is a strong, independent predictor of progression to severe heart failure and death²

1. J Am Coll Cardiol 2016;67:1399-1409
2. N Engl J Med 2003;348:295-303

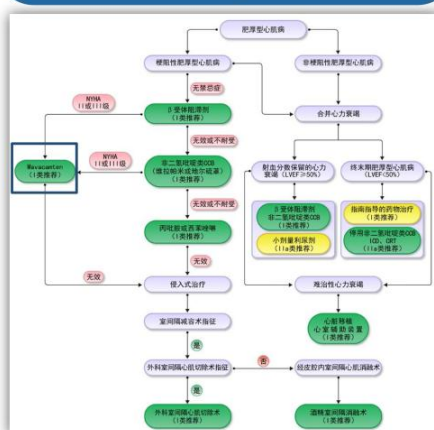


Treatment goals: relieving clinical symptoms, improving cardiac function, delaying disease progression, and reducing disease death¹



1. Clin J Heart Fail & Cardiomyopathy 2022;6:80-105
2. Circulation 2020;142:e558-e631

Mavacamten is recommended in the latest China HCM guidelines



Treatment flow chart of oHCM*

Clin J Heart Fail & Cardiomyopathy 2022;6:80-105

* Mavacamten not approved in China at time of publication

HCM patient advocacy group (肥厚型心肌病病友关爱之家) organized symposium on new modalities in the treatment of HCM



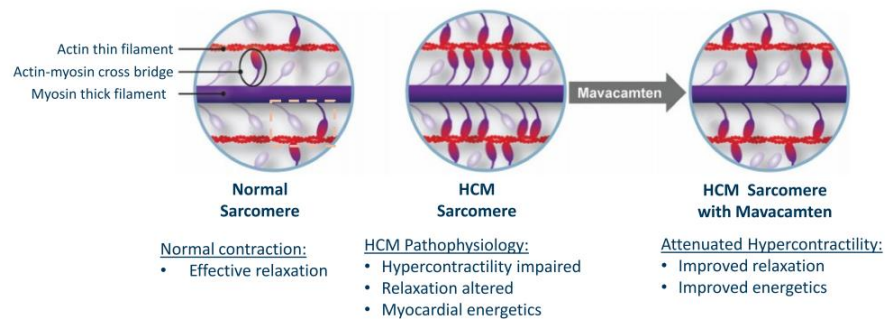


Michael Humphries, FRCP

Chief Scientific Advisor, LianBio

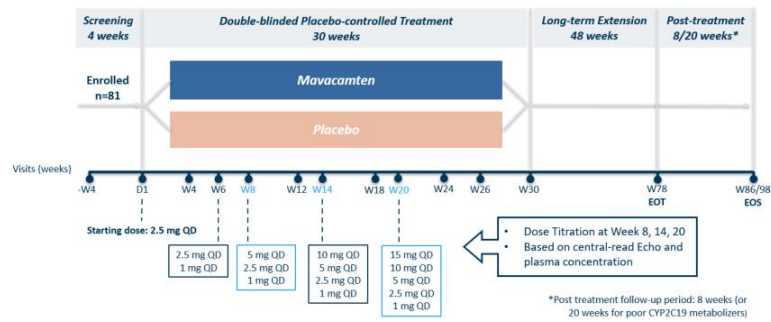
Mechanism of Action

- Mavacamten is a first-in-class myosin inhibitor that targets the excessive contractility and impaired relaxation, myocardial energetics and compliance, with the intent of correcting the abnormal function of the hypertrophic cardiomyopathy (HCM) heart.
- **Primary mechanism** of mavacamten-mediated inhibition of cardiac myosin is the decrease of phosphate release from β -cardiac myosin-S1
- **Secondary mechanism** is the decrease in the number of actin-binding heads transitioning from the weakly to the strongly bound state, which occurs before phosphate release and may provide an additional method to modulate myosin function¹



EXPLORER-CN Study Design

A Phase III, Randomized, Double-Blinded, Placebo-Controlled Study



Key inclusion criteria:

- Aged 18 years or older
- Diagnosed with obstructive hypertrophic cardiomyopathy
- Body weight > 45 kg
- LVEF \geq 55% at rest
- Resting or Valsalva LVOT peak gradient (\geq 50 mmHg) at screening

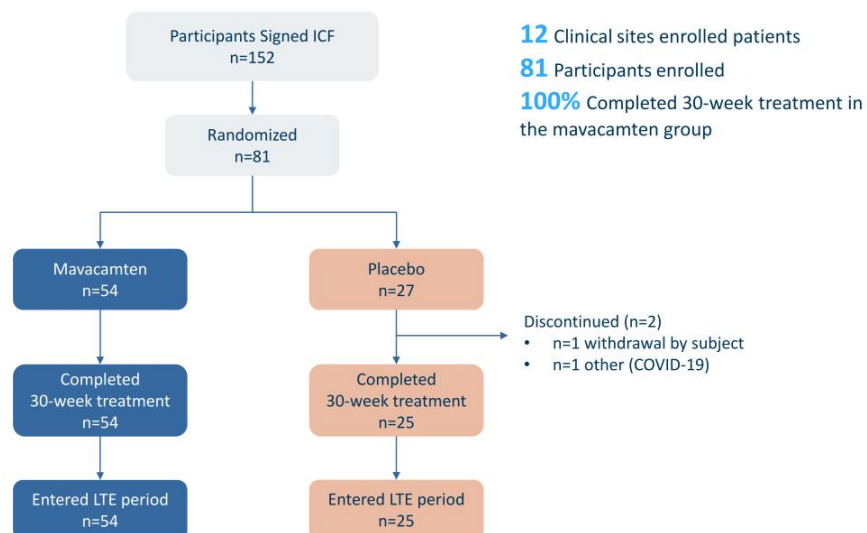
Primary endpoint:

- Change from baseline to week 30 in Valsalva LVOT gradient

Secondary endpoints:

- Change from baseline in resting LVOT peak gradient
- Proportion of participants achieving Valsalva LVOT peak gradient <30 mmHg
- Proportion of participants achieving Valsalva LVOT peak gradient <50 mmHg
- Proportion of participants with \geq 1 NYHA class improvement from baseline
- Change from baseline in KCCQ-CSS
- Change from baseline in NT-proBNP
- Change from baseline in cardiac troponin
- Change from baseline in LVMI evaluated by CMR

EOS, end of study; EOT, end of treatment; LVOT, left ventricular outflow tract; NYHA, New York Heart Association; oHCM, obstructive hypertrophic cardiomyopathy; QD, once daily



	Mavacamten (n=54)	Placebo (n=27)
Age, years, mean (SD)	52.4 (12.1)	51.0 (11.8)
Sex, n (%)		
Male	41 (75.9)	17 (63.0)
Female	13 (24.1)	10 (37.0)
BMI, mean (SD)	25.17 (3.46)	26.11 (3.58)
NYHA Class, n (%)		
Class II	44 (81.5)	18 (66.7)
Class III	10 (18.5)	9 (33.3)
Background HCM therapy, n (%)		
β blocker	48 (88.9)	24 (88.9)
Calcium channel blocker	4 (7.4)	2 (7.4)
Other	2 (3.7)	1 (3.7)

BMI, body mass index; IM, intermediate metabolizer; NM, normal metabolizer; NYHA, New York Heart Association; PM, poor metabolizer; SD, standard deviation

Echocardiographic parameters, mean (SD)	Mavacamten (n=54)	Placebo (n=27)
Resting LVOT peak gradient, mmHg	74.62 (35.05)	73.41 (32.23)
Valsalva LVOT peak gradient, mmHg	106.78 (43.23)	99.79 (41.10)
LVEF, %	77.80 (6.89)	77.00 (6.73)
Maximum LV wall thickness, mm	22.87 (4.93)	24.34 (6.35)
Left atrial volume index, mL/m ²	43.33 (12.15)	47.47 (14.75)

LV, left ventricular; LVEF, left ventricular ejection fraction; LVOT, left ventricular outflow tract; SD, standard deviation

Topline Safety Summary*

- Mavacamten demonstrated a safety profile consistent with past studies, with no new safety signals observed
- Incidence of treatment-emergent adverse events (TEAEs) on mavacamten arm similar to placebo arm
- All treatment-emergent serious adverse events (TESAEs) considered not related to study drug
- No cases of heart failure or death

Protocol-Driven Temporary Treatment Discontinuation

Criteria	Mavacamten (n=54)	Placebo (n=27)
Resting LVEF <50% by core Laboratory	0	0
Pre-dose plasma drug concentration ≥ 1000 ng/mL	1 (1.9%)	0
Both	0	0

- 1 participant in the mavacamten group had dose interruption due to pre-dose plasma drug concentration ≥ 1000 ng/mL. The LVEF was normal and study medication was later resumed.
- No participant had temporary treatment discontinuation or dose interruption due to LVEF <50%

*Full safety data to be presented at an upcoming medical meeting

- Mavacamten demonstrated a statistically significant improvement in Valsalva LVOT gradient from baseline to week 30 with a LSM difference of -70.29 mmHg compared to placebo ($p < 0.001$)
- Data illustrates improvement in Valsalva LVOT gradient in mavacamten group compared to placebo group as early as 4 weeks and sustained through the study period

	Mavacamten (n=54)	Placebo (n=27)	LSM Difference [^] (95% CI)	p-value
Change from baseline to Week 30 in Valsalva LVOT peak gradient, mmHg, mean (SD)	-57.93 (45.61)	20.65 (46.45)	-70.29 (-89.64, -50.94)	<0.001

[^] Model estimated least-square mean differences were reported for continuous variables
CI, confidence interval; LSM, least squares mean; LVOT, left ventricular outflow tract; SD, standard deviation;

- Mavacamten demonstrated treatment benefit across all pre-specified secondary endpoints

Secondary Endpoints*	Mavacamten (n=54)	Placebo (n=27)	Difference (95% CI)^	Nominal p-value**
Change from baseline to Week 30 in Resting LVOT peak gradient, mmHg, mean (SD)	-51.45 (35.99)	6.38 (34.36)	-54.99 (-69.13, -40.86)	<0.001
Proportion of participants achieving a Valsalva LVOT peak gradient <30 mmHg at Week 30, n (%)	26 (48.1)	1 (3.7)	0.41 (0.24, 0.57)	<0.001
Proportion of participants achieving a Valsalva LVOT peak gradient <50 mmHg at Week 30, n (%)	32 (59.3)	2 (7.4)	0.47 (0.30, 0.64)	<0.001
Proportion of participants with at least 1 class improvement in NYHA functional classification from baseline to Week 30, n (%)	32 (59.3)	4 (14.8)	0.39 (0.20, 0.58)	<0.001
Change from baseline to Week 30 in KCCQ-CSS, LSM (SE)	4.99 (2.06)	-5.25 (2.75)	10.24 (4.35, 16.13)	<0.001
Change from baseline to Week 30 in LVMI (CMR), mean (SD)***	-26.37 (21.06)	4.43 (14.42)	-30.80 (-41.55, -20.05)	<0.001

*Due to China HGRAC regulations, biomarker data are not shown. These data will be presented at an upcoming medical meeting

^ Model estimated least-square mean differences were reported for continuous variables

**P-values shown for descriptive purposes only, not multiplicity-adjusted

*** CMR set: mavacamten n=39, placebo n=19

CMR, cardiac magnetic resonance; LVMI, left ventricular mass index; LVOT, left ventricular outflow tract; NYHA, New York Heart Association; SD, standard deviation; KCCQ-CSS, Kansas City Cardiomyopathy Questionnaire-Clinical Summary Score; LSM, least squares mean

- **EXPLORER-CN met the study's primary endpoint with high statistical significance ($p < 0.001$)**
 - Mavacamten showed a significant and **clinically important improvement** in change from baseline to Week 30 in Valsalva LVOT peak gradient by a LSM difference of -70.29 mmHg compared to placebo.
- **Mavacamten showed improvements versus placebo from baseline to Week 30 in all secondary endpoints, including:**
 - Change from baseline in resting LVOT peak gradient
 - Proportion of participants achieving Valsalva LVOT peak gradient < 30 mmHg
 - Proportion of participants achieving Valsalva LVOT peak gradient < 50 mmHg
 - Proportion of participants with ≥ 1 NYHA class improvement from baseline
 - Change from baseline in KCCQ-CSS
 - Change from baseline in LVMI evaluated by CMR
- **Mavacamten demonstrated a safety profile consistent with past studies**
 - There were no new safety signals observed in Chinese patients with oHCM
- **No participant had temporary treatment discontinuation or dose interruption due to LVEF $< 50\%$**



*Data Included in China NDA Package

Global pivotal Phase 3 EXPLORER-HCM trial data

Phase 1 pharmacokinetics study of mavacamten in healthy Chinese volunteers

Blinded preliminary safety data from Phase 3 EXPLORER-CN trial



**Mavacamten Potential in Other
Diseases of Diastolic
Dysfunction**



Brianna Sun

Cardiovascular Medical Head, LianBio

Disease overview

- nHCM has no significant LVOT obstruction (e.g., <30 mmHg) at rest or with provocation
- Driven by diastolic impairment due to the enlarged and stiffened heart muscle
 - ~1/3 of HCM patients have nHCM

Mavacamten treatment rationale

- By altering the contractile mechanics of the cardiomyocyte, mavacamten may have the potential to reduce cardiac filling pressures and improve symptoms associated with non-obstructive HCM

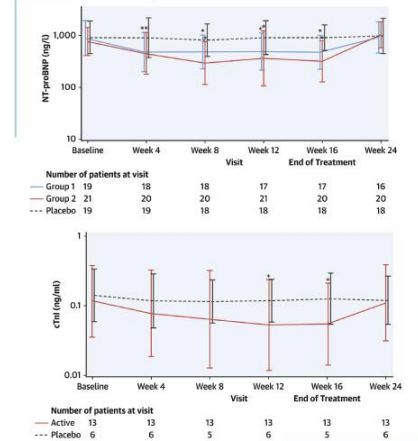
Development pathway

- BMS initiated a Phase 3 trial of mavacamten in nHCM, ODYSSEY-HCM, in 2022

1. J Am Coll Cardiol. 2020 Jun 2;75(21):2649-2660

LVOT, left ventricular outflow tract; NT-proBNP, N-terminal pro-B-type natriuretic peptide; cTnI, cardiac troponin I

Phase 2 MAVERICK-HCM Trial¹



- Physiologic benefits demonstrated with dose dependent reduction in serum levels of NT-proBNP and cTnI, suggesting improvement in cardiac wall stress and myocardial injury



Disease overview

- HFpEF is a disease in which the heart's ability to pump blood through the body is decreased due to the inability of the ventricle to fully relax and fill with blood
- At a cellular level, cardiac myocytes in patients with HFpEF are thicker and shorter than normal myocytes, and collagen content is increased

Mavacamten treatment rationale

- In a subset of HFpEF patients, the underlying cause of symptoms is similar to nHCM, and we believe mavacamten has the potential to address underlying pathophysiology in this subset of HFpEF patients
 - LV diastolic dysfunction
 - Left atrial enlargement
 - Elevated LV filling pressure
 - Myocardial injury & fibrosis
 - LV hypertrophy
 - Abnormal myocardial energetics

Development pathway

- BMS Phase 2a EMBARK-HFpEF trial of mavacamten in HFpEF patients with elevated NT-proBNP ongoing (NCT04766892)
 - Study designed to assess safety, tolerability, and preliminary efficacy of mavacamten on biomarker levels in participants with HFpEF and elevation of NT-proBNP with or without elevation of cTnT

- There are approximately 3.7 million HFpEF patients in China
- Approximately 10-20% of HFpEF patients share similar pathophysiology with nHCM
- Mavacamten may have the potential to treat the underlying pathophysiology

NT-proBNP, N-terminal pro-B-type natriuretic peptide;
cTnT, cardiac troponin T



**Mavacamten China Market
Opportunity**



Pascal Qian

Chief Commercial Officer and General Manager of China,
LianBio



HCM Epidemiology

- There are **1.1-2.8 million potential HCM patients** in China with 0.2%¹ prevalence rate
- oHCM contributes 67% of overall HCM patients and nHCM contributes 33% of overall HCM patients



Diagnosis Opportunity

- Diagnosis rate in China is estimated at ~20%, with the potential for improvement through disease education campaigns
- Current standard diagnostic process needs to be improved including the application of provocation echo



Treatment Opportunity

- No currently available therapy treats underlying disease
- Reach patients across China by leveraging COEs



\$500M

Peak Year Sales
(w. additional indications)

- oHCM
- nHCM
- HFpEF

1. 2023 Guideline for Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy, Chinese Circulation Journal, January ,2023, Vol. 38 No.1 (Serial No.295)

120,000-180,000 diagnosed oHCM patients today with potential to reach 300,000 diagnosed oHCM patients



Efficient coverage through phased approach

~400 level III hospitals:
~20% diagnosed patients

Launch

~1,500 Level II/III hospitals:
(2,000 prescriber ~55% diagnosed patients)

Self-Pay

~3,000 Level II/III hospitals:
(7,000 prescribers ~80% diagnosed patients)

Post-NRDL

~13,000 Level I/II/III hospitals: ~100% diagnosed patients



HCM COE Build



中國心血管健康聯盟
Chinese Cardiovascular Association
Lianbio

- Partnership with Chinese Cardiovascular Association
- Leverage existing infrastructure of heart failure COE
- Lead by top KOLs who built heart failure COE



- Steering Committee
- Pilot wave



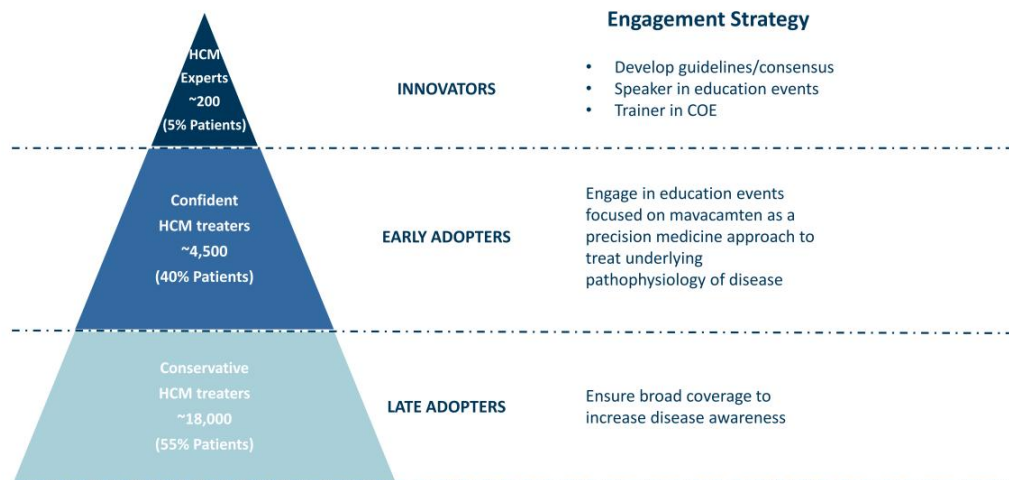
- Build standardized diagnosis and treatment



- Maximize Mavacamten uptake through standardized treatment



Physician segmentation



LianBio vision: Establish myosin inhibitor class as the **new standard of care** for oHCM by maximizing mavacamten's value as the only **treatment targeting the underlying pathophysiology of disease**



Collaboration with China Cardiovascular Association,
Largest local cardiovascular medical society



Support Cardiovascular Foundation to
develop the 1st HCM patient management
and education platform



Collaboration with top institutions for
mavacamten pricing and access strategy

		<ul style="list-style-type: none"> Mavacamten pharmacoeconomic project oHCM burden of disease project
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Company management available for Q&A

- Yizhe Wang, Ph.D., CEO
- Yi Larson, CFO
- Pascal Qian, CCO and General Manager of China
- Michael Humphries, FRCP, Chief Scientific Advisor



EXPLORER-CN Topline Data Results and Mavacamten China Commercial Opportunity Call

May 1, 2023

